UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

October 12, 2004

SUBJECT: PRODUCT CHEMISTRY REVIEW OF:
Sterilex Ultra Disinfectant Cleaner Solution 1

DP Barcode: D307222 **Reg. No. Or File Symbol: 63761-I**
Manufacturing-use [ ] OR **End-use Product [X]**

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Product Formulation from label

Active Ingredient(s)	**% by wt.**
n-Alkyl (C_{12} 68%, C_{14} 32%) ethylbenzyl ammonium chloride	3.00 %
n-Alkyl (C_{14} 60%, C_{16} 30%, C_{12} 5%, C_{18} 5%) benzyl ammonium chloride	3.00 %
Hydrogen peroxide	6.3 %

BACKGROUND:

The registrant has submitted a product chemistry package in support of a "me-too" registration (of 63761-3) of an end-use disinfectant. The package includes a Confidential Statement of Formula, a label, and MRID's 460335-01 and 4636001.

FINDINGS:

1. The concentrations of the active ingredients on the Confidential Statement of Formula (CSF dated 4 June 2004) are consistent with the label declaration. The name of the source of two active ingredients is [redacted]

2. On the CSF, the amount of [redacted] is mistyped in column 13a. It should be typed as [redacted] and not [redacted]. This must be corrected on the CSF.

3. The descriptions of the starting materials and the manufacturing process are **acceptable**.

4. The discussion of the formation of impurities is **acceptable**.

5. The preliminary analysis is **acceptable**.

6. The certified limits are **unacceptable** For [redacted] is not in between the values of [redacted]

7. The analytical enforce methods for the active ingredients are **unacceptable** because they were not submitted with the submission. The analytical enforcement methods for all the active ingredients (both quaternary compounds and hydrogen peroxide) must be submitted. [redacted]

8. The color, physical state, and odor of the product are **acceptable**. The test material is a clear, colorless liquid with no odor.

9. The relative density is **acceptable**. The relative density was determined to be 1.0198 using CIPAC MT 3.

10. The pH is **acceptable** as it was determined to be 5.65 using ASTM E70.

11. The oxidation/reduction potential is **acceptable**. No reaction was observed with water. After 24-hour contact with the product, the ammonium dihydrogen phosphate completely went into with no change in temperature or appearance. When the product was placed into contact with an iron coupon, bubbles immediately arose from the coupon. An orange foam began to accumulate on the upper surface of the solution after five minutes. After 30 minutes, the solution had turned orange and 25 mL of foam had accumulated. After an hour, 70 mL of foam had accumulated and brown streaks appeared on the coupon. After two hours, additional brown

streaks appeared, bubbling continued, but the foam began to subside. After 24 hours, bubbling had ceased and the foam was gone. The coupon was covered with a brown deposit which was rinsed and dried. The mass of the coupon was reduced by 0.201 g. When the product came into contact with potassium permanganate, the solution turned light orange and began effervescing. A white foam began to accumulate at the upper surface of the solution. After twenty minutes, effervescence waned and the foam began to subside. After a day, the solution was clear and colorless.

12. The flammability is **unacceptable**. It is only addressed on the CSF, and nowhere else in the submission. It must be addressed in the physical/chemical properties.

13. The explodability is **unacceptable** because it is not addressed in the submission. It constitutes a data gap.

14. The joint study for storage stability and corrosion characteristics is **unacceptable** because the study was not done under GLP compliance. It is also unacceptable because heating the product will get rid of the hydrogen peroxide contained in the product.

15. The viscosity is **acceptable** because the value of this property was determined to be 1.55 centistokes at 25 °C using CIPAC MT 22.

16. The miscibility of the product is **unacceptable** because it is not addressed in the submission. It constitutes a data gap.

17. The dielectric breakdown voltage is **unacceptable** because it is not addressed in the submission. It constitutes a data gap.

18. Because the proposed product has public health claims and because the product contains hydrogen peroxide, a one year GLP storage stability study must be submitted to the Agency for review.

RECOMMENDATIONS:

1. Product Science Branch of Antimicrobials Division finds this submission in support of the registration of 63761-I to be unacceptable for the reasons discussed in the findings. The registrant must remedy the discrepancies discussed in the findings before registration of this product can proceed.